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Subpart A [Reserved]

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

§ 485.50 Basis and scope.

This subpart sets forth the conditions that facilities must meet to be certified as comprehensive outpatient rehabilitation facilities (CORFs) under section 1861(cc)(2) of the Social Security Act and be accepted for participation in Medicare in accordance with part 489 of this chapter.

§ 485.51 Definition.

As used in this subpart, unless the context indicates otherwise, “*comprehensive outpatient rehabilitation facility*”, “*CORF*”, or “*facility*” means a nonresidential facility that—

(a) Is established and operated exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician; and

(b) Meets all the requirements of this subpart.

§ 485.54 Condition of participation: Compliance with State and local laws.

The facility and all personnel who provide services must be in compliance with applicable State and local laws and regulations.

(a) *Standard: Licensure of facility.* If State or local law provides for licensing, the facility must be currently licensed or approved as meeting the standards established for licensure.

(b) *Standard: Licensure of personnel.* Personnel that provide service must be licensed, certified, or registered in accordance with applicable State and local laws.

§ 485.56 Condition of participation: Governing body and administration.

The facility must have a governing body that assumes full legal responsibility for establishing and implementing policies regarding the management and operation of the facility.

(a) *Standard: Disclosure of ownership.* The facility must comply with the provisions of part 420, subpart C of this chapter that require health care providers and fiscal agents to disclose certain information about ownership and control.

(b) *Standard: Administrator.* The governing body must appoint an administrator who—

(1) Is responsible for the overall management of the facility under the authority delegated by the governing body;

(2) Implements and enforces the facility’s policies and procedures;

(3) Designates, in writing, an individual who, in the absence of the administrator, acts on behalf of the administrator; and

(4) Retains professional and administrative responsibility for all personnel providing facility services.

(c) *Standard: Group of professional personnel.* The facility must have a group of professional personnel associated with the facility that—

(1) Develops and periodically reviews policies to govern the services provided by the facility; and

(2) Consists of at least one physician and one professional representing each of the services provided by the facility.

(d) *Standard: Institutional budget plan.* The facility must have an institutional budget plan that meets the following conditions:

(1) It is prepared, under the direction of the governing body, by a committee consisting of representatives of the governing body and the administrative staff.

(2) It provides for—

(i) An annual operating budget prepared according to generally accepted accounting principles;

(ii) A 3-year capital expenditure plan if expenditures in excess of \$100,000 are anticipated, for that period, for the acquisition of land; the improvement of land, buildings, and equipment; and the replacement, modernization, and expansion of buildings and equipment; and

(iii) Annual review and updating by the governing body.

(e) *Standard: Patient care policies.* The facility must have written patient care policies that govern the services it furnishes. The patient care policies must include the following:

(1) A description of the services the facility furnishes through employees and those furnished under arrangements.

(2) Rules for and personnel responsibilities in handling medical emergencies.

(3) Rules for the storage, handling, and administration of drugs and biologicals.

(4) Criteria for patient admission, continuing care, and discharge.

(5) Procedures for preparing and maintaining clinical records on all patients.

(6) A procedure for explaining to the patient and the patient's family the extent and purpose of the services to be provided.

(7) A procedure to assist the referring physician in locating another level of care for—patients whose treatment has terminated and who are discharged.

(8) A requirement that patients accepted by the facility must be under the care of a physician.

(9) A requirement that there be a plan of treatment established by a physician for each patient.

(10) A procedure to ensure that the group of professional personnel reviews and takes appropriate action on recommendations from the utilization review committee regarding patient care policies.

(f) *Standard: Delegation of authority.* The responsibility for overall administration, management, and operation must be retained by the facility itself and not delegated to others.

(1) The facility may enter into a contract for purposes of assistance in financial management and may delegate to others the following and similar services:

(i) Bookkeeping.

(ii) Assistance in the development of procedures for billing and accounting systems.

(iii) Assistance in the development of an operating budget.

(iv) Purchase of supplies in bulk form.

(v) The preparation of financial statements.

(2) When the services listed in paragraph (f)(1) of this section are delegated, a contract must be in effect and:

(i) May not be for a term of more than 5 years;

(ii) Must be subject to termination within 60 days of written notice by either party;

(iii) Must contain a clause requiring renegotiation of any provision that CMS finds to be in contravention to any new, revised or amended Federal regulation or law;

(iv) Must state that only the facility may bill the Medicare program; and

(v) May not include clauses that state or imply that the contractor has power and authority to act on behalf of the facility, or clauses that give the contractor rights, duties, discretions, or responsibilities that enable it to dictate the administration, management, or operations of the facility.

§ 485.58 Condition of participation: Comprehensive rehabilitation program.

The facility must provide a coordinated rehabilitation program that includes, at a minimum, physicians' services, physical therapy services, and social or psychological services. The services must be furnished by personnel that meet the qualifications set forth in § 485.70 and must be consistent with the plan of treatment and the results of comprehensive patient assessments.

(a) *Standard: Physician services.* (1) A facility physician must be present in the facility for a sufficient time to—

(i) Provide, in accordance with accepted principles of medical practice, medical direction, medical care services, and consultation;

(ii) Establish the plan of treatment in cases where a plan has not been established by the referring physician;

(iii) Assist in establishing and implementing the facility's patient care policies; and

(iv) Participate in plan of treatment reviews, patient case review conferences, comprehensive patient assessment and reassessments, and utilization review.

(2) The facility must provide for emergency physician services during the facility operating hours.

(b) *Standard: Plan of treatment.* For each patient, a physician must establish a plan of treatment before the facility initiates treatment. The plan of treatment must meet the following requirements:

(1) It must delineate anticipated goals and specify the type, amount, frequency and duration of services to be provided.

(2) It must be promptly evaluated after changes in the patient's condition and revised when necessary.

(3) It must, if appropriate, be developed in consultation with the facility physician and the appropriate facility professional personnel.

(4) It must be reviewed at least every 60 days by a facility physician who, when appropriate, consults with the professional personnel providing services. The results of this review must be communicated to the patient's referring physician for concurrence before treatment is continued or discontinued.

(5) It must be revised if the comprehensive reassessment of the patient's status or the results of the patient case review conference indicate the need for revision.

(c) *Standard: Coordination of services.* The facility must designate, in writing, a qualified professional to ensure that professional personnel coordinate their related activities and exchange information about each patient under their care. Mechanisms to assist in the coordination of services must include—

(1) Providing to all personnel associated with the facility, a schedule indicating the frequency and type of services provided at the facility;

(2) A procedure for communicating to all patient care personnel pertinent information concerning significant changes in the patient's status;

(3) Periodic clinical record entries, noting at least the patient's status in relationship to goal attainment; and

(4) Scheduling patient case review conferences for purposes of determining appropriateness of treatment, when indicated by the results of the initial comprehensive patient assessment, reassessment(s), the recommendation of the facility physician (or other physician who established the plan of treatment), or upon the rec-

ommendation of one of the professionals providing services.

(d) *Standard: Provision of services.* (1) All patients must be referred to the facility by a physician who provides the following information to the facility before treatment is initiated:

(i) The patient's significant medical history.

(ii) Current medical findings.

(iii) Diagnosis(es) and contraindications to any treatment modality.

(iv) Rehabilitation goals, if determined.

(2) Services may be provided by facility employees or by others under arrangements made by the facility.

(3) The facility must have on its premises the necessary equipment to implement the plan of treatment and sufficient space to allow adequate care.

(4) The services must be furnished by personnel that meet the qualifications of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in § 485.70 may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities.

(5) A qualified professional must initiate and coordinate the appropriate portions of the plan of treatment, monitor the patient's progress, and recommend changes, in the plan, if necessary.

(6) A qualified professional representing each service made available at the facility must be either on the premises of the facility or must be available through direct telecommunication for consultation and assistance during the facility's operating hours. At least one qualified professional must be on the premises during the facility's operating hours.

(7) All services must be provided consistent with accepted professional standards and practice.

(e) *Standard: Scope and site of services—*(1) *Basic requirements.* The facility

must provide all the CORF services required in the plan of treatment and, except as provided in paragraph (e)(2) of this section, must provide the services on its premises.

(2) *Exceptions.* Physical therapy, occupational therapy, and speech pathology services furnished away from the premises of the CORF may be covered as CORF services if Medicare payment is not otherwise made for these services. In addition, a single home visit is covered if there is need to evaluate the potential impact of the home environment on the rehabilitation goals.

(f) *Standard: Patient assessment.* Each qualified professional involved in the patient's care, as specified in the plan of treatment, must—

(1) Carry out an initial patient assessment; and

(2) In order to identify whether or not the current plan of treatment is appropriate, perform a patient reassessment after significant changes in the patient's status.

(g) *Standard: Laboratory services.* (1) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

[48 FR 56293, Dec. 15, 1982, as amended at 56 FR 8852, Mar. 1, 1991; 57 FR 7137, Feb. 28, 1992]

§ 485.60 Condition of participation: Clinical records.

The facility must maintain clinical records on all patients in accordance with accepted professional standards and practice. The clinical records must be completely, promptly, and accurately documented, readily accessible, and systematically organized to facilitate retrieval and compilation of information.

(a) *Standard: Content.* Each clinical record must contain sufficient information to identify the patient clearly and to justify the diagnosis and treatment. Entries in the clinical record must be made as frequently as is nec-

essary to insure effective treatment and must be signed by personnel providing services. All entries made by assistant level personnel must be countersigned by the corresponding professional. Documentation on each patient must be consolidated into one clinical record that must contain—

(1) The initial assessment and subsequent reassessments of the patient's needs;

(2) Current plan of treatment;

(3) Identification data and consent or authorization forms;

(4) Pertinent medical history, past and present;

(5) A report of pertinent physical examinations if any;

(6) Progress notes or other documentation that reflect patient reaction to treatment, tests, or injury, or the need to change the established plan of treatment; and

(7) Upon discharge, a discharge summary including patient status relative to goal achievement, prognosis, and future treatment considerations.

(b) *Standard: Protection of clinical record information.* The facility must safeguard clinical record information against loss, destruction, or unauthorized use. The facility must have procedures that govern the use and removal of records and the conditions for release of information. The facility must obtain the patient's written consent before releasing information not required to be released by law.

(c) *Standard: Retention and preservation.* The facility must retain clinical record information for 5 years after patient discharge and must make provision for the maintenance of such records in the event that it is no longer able to treat patients.

§ 485.62 Condition of participation: Physical environment.

The facility must provide a physical environment that protects the health and safety of patients, personnel, and the public.

(a) *Standard: Safety and comfort of patients.* The physical premises of the facility and those areas of its surrounding physical structure that are used by the patients (including at least

all stairwells, corridors and passageways) must meet the following requirements:

(1) Applicable Federal, State, and local building, fire, and safety codes must be met.

(2) Fire extinguishers must be easily accessible and fire regulations must be prominently posted.

(3) A fire alarm system with local (in-house) capability must be functional, and where power is generated by electricity, an alternate power source with automatic triggering must be present.

(4) Lights, supported by an emergency power source, must be placed at exits.

(5) A sufficient number of staff to evacuate patients during a disaster must be on the premises of the facility whenever patients are being treated.

(6) Lighting must be sufficient to carry out services safely; room temperature must be maintained at comfortable levels; and ventilation through windows, mechanical means, or a combination of both must be provided.

(7) Safe and sufficient space must be available for the scope of services offered.

(b) *Standard: Sanitary environment.* The facility must maintain a sanitary environment and establish a program to identify, investigate, prevent, and control the cause of patient infections.

(1) The facility must establish written policies and procedures designed to control and prevent infection in the facility and to investigate and identify possible causes of infection.

(2) The facility must monitor the infection control program to ensure that the staff implement the policies and procedures and that the policies and procedures are consistent with current practices in the field.

(3) The facility must make available at all times a quantity of laundered linen adequate for proper care and comfort of patients. Linens must be handled, stored, and processed in a manner that prevents the spread of infection.

(4) Provisions must be in effect to ensure that the facility's premises are maintained free of rodent and insect infestation.

(c) *Standard: Maintenance of equipment, physical location, and grounds.*

The facility must establish a written preventive maintenance program to ensure that—

(1) All equipment is properly maintained and equipment needing periodic calibration is calibrated consistent with the manufacturer's recommendations; and

(2) The interior of the facility, the exterior of the physical structure housing the facility, and the exterior walkways and parking areas are clean and orderly and maintained free of any defects that are a hazard to patients, personnel, and the public.

(d) *Standard: Access for the physically impaired.* The facility must ensure the following:

(1) Doorways, stairwells, corridors, and passageways used by patients are—

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs); and

(ii) In the case of stairwells, equipped with firmly attached handrails on at least one side.

(2) At least one toilet facility is accessible and constructed to allow utilization by ambulatory and non-ambulatory individuals.

(3) At least one entrance is usable by individuals in wheelchairs.

(4) In multi-story buildings, elevators are accessible to and usable by the physically impaired on the level that they use to enter the building and all levels normally used by the patients of the facility.

(5) Parking spaces are large enough and close enough to the facility to allow safe access by the physically impaired.

§ 485.64 Condition of participation: Disaster procedures.

The facility must have written policies and procedures that specifically define the handling of patients, personnel, records, and the public during disasters. All personnel associated with the facility must be knowledgeable with respect to these procedures, be trained in their application, and be assigned specific responsibilities.

(a) *Standard: Disaster plan.* The facility's written disaster plan must be developed and maintained with assistance of qualified fire, safety, and other

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appropriate experts. The plan must include—

(1) Procedures for prompt transfer of casualties and records;

(2) Procedures for notifying community emergency personnel (for example, fire department, ambulance, etc.);

(3) Instructions regarding the location and use of alarm systems and signals and fire fighting equipment; and

(4) Specification of evacuation routes and procedures for leaving the facility.

(b) *Standard: Drills and staff training.*

(1) The facility must provide ongoing training and drills for all personnel associated with the facility in all aspects of disaster preparedness.

(2) All new personnel must be oriented and assigned specific responsibilities regarding the facility's disaster plan within two weeks of their first workday.

§ 485.66 Condition of participation: Utilization review plan.

The facility must have in effect a written utilization review plan that is implemented at least each quarter, to assess the necessity of services and promotes the most efficient use of services provided by the facility.

(a) *Standard: Utilization review committee.* The utilization review committee, consisting of the group of professional personnel specified in § 485.56(c), a committee of this group, or a group of similar composition, comprised by professional personnel not associated with the facility, must carry out the utilization review plan.

(b) *Standard: Utilization review plan.* The utilization review plan must contain written procedures for evaluating—

(1) Admissions, continued care, and discharges using, at a minimum, the criteria established in the patient care policies;

(2) The applicability of the plan of treatment to established goals; and

(3) The adequacy of clinical records with regard to—

(i) Assessing the quality of services provided; and

(ii) Determining whether the facility's policies and clinical practices are compatible and promote appropriate and efficient utilization of services.

§ 485.70 Personnel qualifications.

This section sets forth the qualifications that must be met, as a condition of participation, under § 485.58, and as a condition of coverage of services under § 410.100 of this chapter.

(a) A facility physician must be a doctor of medicine or osteopathy who—

(1) Is licensed under State law to practice medicine or surgery; and

(2) Has had, subsequent to completing a 1-year hospital internship, at least 1 year of training in the medical management of patients requiring rehabilitation services; or

(3) Has had at least 1 year of full-time or part-time experience in a rehabilitation setting providing physicians' services similar to those required in this subpart.

(b) A licensed practical nurse must be licensed as a practical or vocational nurse by the State in which practicing, if applicable.

(c) An occupational therapist and an occupational therapist assistant must meet the qualifications set forth in § 405.1202(f) and (g) of this chapter.

(d) An orthotist must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in orthotics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in orthotics.

(e) A *physical therapist* and a *physical therapist assistant* must meet the qualifications set forth in paragraphs (b) and (c) of § 485.705.

(f) A *prosthetist* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program in prosthetics that is jointly recognized by the American Council on Education and the American Board for Certification in Orthotics and Prosthetics; and

(3) Be eligible to take that Board's certification examination in prosthetics.

(g) A *psychologist* must be certified or licensed by the State in which he or she is practicing, if that State requires certification or licensing, and must

hold a masters degree in psychology from an educational institution approved by the State in which the institution is located.

(h) A *registered nurse* must be a graduate of an approved school of nursing and be licensed as a registered nurse by the State in which practicing, if applicable.

(i) A *rehabilitation counselor* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree; and

(3) Be eligible to take the certification examination administered by the Commission on Rehabilitation Counselor Certification.

(j) A *respiratory therapist* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committee on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the registry examination for respiratory therapists administered by the National Board for Respiratory Therapy, Inc.; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(k) A *respiratory therapy technician* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Have successfully completed a training program accredited by the Committees on Allied Health Education and Accreditation (CAHEA) in collaboration with the Joint Review Committee for Respiratory Therapy Education; and

(3) Either—

(i) Be eligible to take the certification examination for respiratory therapy technicians administered by the National Board for Respiratory Therapy, Inc.; or

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Therapy, Inc.

(l) A *social worker* must—

(1) Be licensed by the State in which practicing, if applicable;

(2) Hold at least a bachelor's degree from a school accredited or approved by the Council on Social Work Education; and

(3) Have 1 year of social work experience in a health care setting.

(m) A *speech-language pathologist* must meet the qualifications set forth in § 485.705(f) of this chapter.

[48 FR 56293, Dec. 15, 1982. Redesignated and amended at 50 FR 33034, Aug. 16, 1985; 51 FR 41352, Nov. 14, 1986; 60 FR 2327, Jan. 9, 1995]

§ 485.74 Appeal rights.

The appeal provisions set forth in part 498 of this chapter, for providers, are applicable to any entity that is participating or seeks to participate in the Medicare program as a CORF.

[48 FR 56293, Dec. 15, 1982, as amended at 52 FR 22454, June 12, 1987]

Subparts C-E [Reserved]

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

SOURCE: 58 FR 30671, May 26, 1993, unless otherwise noted.

§ 485.601 Basis and scope.

(a) *Statutory basis.* This subpart is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.

(b) *Scope.* This subpart sets forth the conditions that a hospital must meet to be designated as a CAH.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.602 Definitions.

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by employed staff of the CAH, not services provided through arrangements or agreements.

[59 FR 45403, Sept. 1, 1994, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.603 Rural health network.

A rural health network is an organization that meets the following specifications:

(a) It includes—

(1) At least one hospital that the State has designated or plans to designate as a CAH; and

(2) At least one hospital that furnishes acute care services.

(b) The members of the organization have entered into agreements regarding—

(1) Patient referral and transfer;

(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and

(3) The provision of emergency and nonemergency transportation among members.

(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least—

(1) One hospital that is a member of the network when applicable;

(2) One PRO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46035, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

§ 485.604 Personnel qualifications.

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) *Clinical nurse specialist.* A clinical nurse specialist must be a person who performs the services of a clinical nurse specialist as authorized by the State, in accordance with State law or the State regulatory mechanism provided by State law.

(b) *Nurse practitioner.* A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a 1 academic year program that—

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

(c) *Physician assistant.* A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that—

(i) Was at least one academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.606 Designation and certification of CAHs.

(a) *Criteria for State designation.* (1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this subpart F.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may provide posthospital SNF care as described in § 482.66 of this chapter.

(b) *Criteria for CMS certification.* CMS certifies a facility as a CAH if—

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this Part and all other applicable requirements for participation in Part 489 of this chapter.

(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997, and is otherwise eligible to be designated as a CAH by the State under the rules in this subpart.

[62 FR 46036, Aug. 29, 1997, as amended at 63 FR 26359, May 12, 1998]

§ 485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) *Standard: Compliance with Federal laws and regulations.* The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

(b) *Standard: Compliance with State and local laws and regulations.* All patient care services are furnished in accordance with applicable State and local laws and regulations.

(c) *Standard: Licensure of CAH.* The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

(d) *Standard: Licensure, certification or registration of personnel.* Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.610 Condition of participation: Status and location.

(a) *Standard: Status.* The facility is—

(1) A currently participating hospital that meets all conditions of participation set forth in this subpart;

(2) A recently closed facility, provided that the facility—

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that—

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

(b) *Standard: Location in a rural area or treatment as rural.* The CAH meets the requirements of either paragraph (b)(1) or (b)(2) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under § 412.62(f) of this chapter;

(ii) The CAH is not deemed to be located in an urban area under § 412.63(b) of this chapter; and

(iii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under § 412.230(e) of this chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under § 412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined

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by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with § 412.103 of this chapter.

(c) *Standard: Location relative to other facilities or necessary provider certification.* The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or the CAH is certified by the State as being a necessary provider of health care services to residents in the area.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 66 FR 39938, Aug. 1, 2001]

§ 485.612 Condition of participation: Compliance with hospital requirements at the time of application.

Except for recently closed facilities as described in § 485.610(a)(2), or health clinics or health centers as described in § 485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

[66 FR 32196, June 13, 2001]

§ 485.616 Condition of participation: Agreements.

(a) *Standard: Agreements with network hospitals.* In the case of a CAH that is a member of a rural health network as defined in § 485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for—

- (1) Patient referral and transfer;
- (2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

(3) The provision of emergency and nonemergency transportation between the facility and the hospital.

(b) *Standard: Agreements for credentialing and quality assurance.* Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least—

- (1) One hospital that is a member of the network;

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- (2) One PRO or equivalent entity; or
- (3) One other appropriate and qualified entity identified in the State rural health care plan.

[62 FR 46036, Aug. 29, 1997]

§ 485.618 Condition of participation: Emergency services.

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

(a) *Standard: Availability.* Emergency services are available on a 24-hours a day basis.

(b) *Standard: Equipment, supplies, and medication.* Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

(1) *Drugs and biologicals* commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrhythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

(2) *Equipment and supplies* commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

(c) *Standard: Blood and blood products.* The facility provides, either directly or under arrangements, the following:

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

(2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

(d) *Standard: Personnel.* There must be a doctor of medicine or osteopathy,

a physician assistant, or a nurse practitioner with training or experience in emergency care on call and immediately available by telephone or radio contact, and available on site within the following timeframes:

(1) Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described in paragraph (d)(2) of this section; or

(2) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(i) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(ii) The State has determined under criteria in its rural health care plan that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(iii) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(e) *Standard: Coordination with emergency response systems.* The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 41544, July 30, 1999]

§ 485.620 Condition of participation: Number of beds and length of stay.

(a) *Standard: Number of beds.* Except as permitted for CAHs having swing-bed agreements under § 485.645 of this

chapter, the CAH maintains no more than 15 inpatient beds.

(b) *Standard: Length of stay.* The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000]

§ 485.623 Condition of participation: Physical plant and environment.

(a) *Standard: Construction.* The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) *Standard: Maintenance.* The CAH has housekeeping and preventive maintenance programs to ensure that—

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

(2) There is proper routine storage and prompt disposal of trash;

(3) Drugs and biologicals are appropriately stored;

(4) The premises are clean and orderly; and

(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

(c) *Standard: Emergency procedures.* The CAH assures the safety of patients in non-medical emergencies by—

(1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

(3) Providing for an emergency fuel and water supply; and

(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

(d) *Standard: Life safety from fire—*(1) Except as provided in paragraphs (d)(2) and (d)(3) of this section, the CAH must meet the requirements of chapter 12, New Health Care Occupancy, or chapter 13, Existing Health Care Occupancy, of the 1985 edition of the Life

Safety Code of the National Fire Protection Association. Incorporation by reference of the 1985 edition of the National Fire Protection Association's Life Safety Code (published February 7, 1985; ANSI/NFPA 101) was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Room C2-07-13, Central Building, Baltimore, MD 21244-1850, and the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, Batterymarch Park, Quincy, Mass. 02209. If any changes in this code are also to be incorporated by reference, a document to that effect will be published in the FEDERAL REGISTER.

(2) Any CAH that as a hospital on or before November 26, 1982, complied, with or without waivers, with the requirements of the 1967 edition of the Life Safety Code, or after November 26, 1982 and on or before May 9, 1988, complied with the 1981 edition of the Life Safety Code, is considered to be in compliance with this standard as long as the CAH continues to remain in compliance with that edition of the Code. The 1967 and 1981 Life Safety Codes are available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Room C2-07-13, Central Building, Baltimore, MD 21244-1850.

(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46036, 46037, Aug. 29, 1997]

§ 485.627 Condition of participation: Organizational structure.

(a) *Standard: Governing body or responsible individual.* The CAH has a governing body or an individual that as-

sumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

(b) *Standard: Disclosure.* The CAH discloses the names and addresses of—

(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;

(2) The person principally responsible for the operation of the CAH; and

(3) The person responsible for medical direction.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.631 Condition of participation: Staffing and staff responsibilities.

(a) *Standard: Staffing—*(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the CAH.

(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

(b) *Standard: Responsibilities of the doctor of medicine or osteopathy.* (1) The doctor of medicine or osteopathy—

(i) Provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff;

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

(iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the latest site visit.

(c) *Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities.* (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff—

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteop-

athy on the staff of the CAH is notified of the admission.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.635 Condition of participation: Provision of services.

(a) *Standard: Patient care policies.* (1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.631(a)(1); at least one member is not a member of the CAH staff.

(3) The policies include the following:

(i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

(ii) Policies and procedures for emergency medical services.

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are

met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of § 483.25(i) is met with respect to inpatients receiving posthospital SNF care.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

(b) *Standard: Direct services*—(1) *General*. The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory services*. The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

- (i) Chemical examination of urine by stick or tablet method or both (including urine ketones);
- (ii) Hemoglobin or hematocrit;
- (iii) Blood glucose;
- (iv) Examination of stool specimens for occult blood;
- (v) Pregnancy tests; and
- (vi) Primary culturing for transmittal to a certified laboratory.

(3) *Radiology services*. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

(4) *Emergency procedures*. In accordance with the requirements of § 485.618, the CAH provides as direct services medical emergency procedures as a first response to common life-threatening injuries and acute illness.

(c) *Standard: Services provided through agreements or arrangements*. (1) The CAH

has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including—

- (i) Inpatient hospital care;
- (ii) Services of doctors of medicine or osteopathy; and
- (iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.
- (iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.

(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.

(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.

(4) The person principally responsible for the operation of the CAH under § 485.627(b)(2) of this chapter is also responsible for the following:

- (i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.
- (ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

(d) *Standard: Nursing services*. Nursing services must meet the needs of patients.

(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.

(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.

(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a

registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.

(4) A nursing care plan must be developed and kept current for each inpatient.

[58 FR 30671, May 26, 1993; 58 FR 49935, Sept. 24, 1993, as amended at 59 FR 45403, Sept. 1, 1994; 62 FR 46037, Aug. 29, 1997]

§ 485.638 Conditions of participation: Clinical records.

(a) *Standard: Records system.*—(1) The CAH maintains a clinical records system in accordance with written policies and procedures.

(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) *Standard: Protection of record information.*—(1) The CAH maintains the confidentiality of record information

and provides safeguards against loss, destruction, or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) *Standard: Retention of records.* The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

§ 485.639 Condition of participation: Surgical services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) *Designation of qualified practitioners.* The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by—

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

(b) *Anesthetic risk and evaluation.*

(1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

(c) *Administration of anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH

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patients in accordance with its approved policies and procedures and with State scope of practice laws.

(1) Anesthetics must be administered only by—

- (i) A qualified anesthesiologist;
- (ii) A doctor of medicine or osteopathy other than an anesthesiologist, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;
- (iii) A doctor of dental surgery or dental medicine;
- (iv) A doctor of podiatric medicine;
- (v) A certified registered nurse anesthetist, as defined in § 410.69(b) of this chapter;
- (vi) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or
- (vii) A supervised trainee in an approved educational program, as described in §§ 413.85 or 413.86 of this chapter.

(2) In those cases in which a certified registered nurse anesthetist administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(d) *Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

[60 FR 45851, Sept. 1, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 66 FR 39938, Aug. 1, 2001]

EFFECTIVE DATE NOTE: At 66 FR 4687, Jan. 18, 2001, § 485.639 was amended by revising paragraph (c), effective Mar. 19, 2001. At 66 FR 15352, Mar. 19, 2001 the effective date was delayed until May 18, 2001, at 66 FR 27598, May 18, 2001 this amendment was further delayed until Nov. 14, 2001. For the convenience of the user, the revised text reads as follows:

§ 485.639 Condition of participation-surgical services.

* * * * *

(c) *Administration of anesthesia.* The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope of practice laws. Anesthesia is administered only by a

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licensed practitioner permitted by the State to administer anesthetics.

* * * * *

§ 485.641 Condition of participation: Periodic evaluation and quality assurance review.

(a) *Standard: Periodic evaluation.*—(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of—

- (i) The utilization of CAH services, including at least the number of patients served and the volume of services;
- (ii) A representative sample of both active and closed clinical records; and
- (iii) The CAH's health care policies.

(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

(b) *Standard: Quality assurance.* The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that—

(1) All patient care services and other services affecting patient health and safety, are evaluated;

(2) Nosocomial infections and medication therapy are evaluated;

(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by—

- (i) One hospital that is a member of the network, when applicable;
- (ii) One PRO or equivalent entity; or
- (iii) One other appropriate and qualified entity identified in the State rural health care plan; and

(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of

the PRO, and takes corrective action if necessary.

(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

(iii) The CAH documents the outcome of all remedial action.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

§ 485.643 Condition of participation: Organ, tissue, and eye procurement.

The CAH must have and implement written protocols that:

(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(f) For purposes of these standards, the term “organ” means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

[65 FR 47110, Aug. 1, 2000, as amended at 66 FR 39938, Aug. 1, 2001]

§ 485.645 Special requirements for CAH providers of long-term care services (“swing-beds”)

A CAH must meet the following requirements in order to be granted an approval from CMS to provided post-hospital SNF care, as specified in § 409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

(a) *Eligibility.* A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under § 485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds, and the number of beds used at any time for acute care inpatient services does not exceed 15 beds. Any bed of a unit of the facility that is licensed as distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

(b) *Facilities participating as rural primary care hospitals (RPCHs) on September 30, 1997.* These facilities must meet the following requirements:

(1) Notwithstanding paragraph (a) of this section, a CAH that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions and limitations that were applicable at the time those approvals were granted.

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(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

(c) *Payment.* Payment for inpatient RPDH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with § 413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in § 413.114 of this chapter.

(d) *SNF services.* The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

(1) Residents rights (§ 483.10(b)(3) through (b)(6), (d) (e), (h), (i), (j)(1)(vii) and (viii), (l), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (§ 483.12(a) of this chapter).

(3) Resident behavior and facility practices (§ 483.13 of this chapter).

(4) Patient activities (§ 483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of § 485.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (§ 483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (§ 483.20 (b), (d), and (e) of this chapter, except that the CAH is not required to comply with the requirements for frequency, scope and number of assessments prescribed in § 413.343(b)).

(7) Specialized rehabilitative services (§ 483.45 of this chapter).

(8) Dental services (§ 483.55 of this chapter).

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(9) Nutrition (§ 483.25(i) of this chapter).

[63 FR 26359, May 12, 1998 as amended at 64 FR 41544, July 30, 1999]

Subpart G [Reserved]

Subpart H—Conditions of Participation for Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

§ 485.701 Basis and scope.

This subpart implements section 1861(p)(4) of the Act, which—

(a) Defines outpatient physical therapy and speech pathology services;

(b) Imposes requirements with respect to adequate program, facilities, policies, staffing, and clinical records; and

(c) Authorizes the Secretary to establish by regulation other health and safety requirements.

[60 FR 2327, Jan. 9, 1995]

§ 485.703 Definitions.

Clinic. A facility that is established primarily to furnish outpatient physician services and that meets the following tests of physician involvement:

(1) The medical services are furnished by a group of three or more physicians practicing medicine together.

(2) A physician is present during all hours of operation of the clinic to furnish medical services, as distinguished from purely administrative services.

Organization. A clinic, rehabilitation agency, or public health agency.

Public health agency. An official agency established by a State or local government, the primary function of which is to maintain the health of the population served by performing environmental health services, preventive medical services, and in certain cases, therapeutic services.

Rehabilitation agency. An agency that—

(1) Provides an integrated multidisciplinary rehabilitation program designed to upgrade the physical functioning of handicapped disabled individuals by bringing specialized rehabilitation staff together to perform as a team; and

(2) Provides at least the following services:

(i) Physical therapy or speech-language pathology services.

(ii) Social or vocational adjustment services.

Supervision. Authoritative procedural guidance that is for the accomplishment of a function or activity and that—

(1) Includes initial direction and periodic observation of the actual performance of the function or activity; and

(2) Is furnished by a qualified person—

(i) Whose sphere of competence encompasses the particular function or activity; and

(ii) Who (unless otherwise provided in this subpart) is on the premises if the person performing the function or activity does not meet the assistant-level practitioner qualifications specified in § 485.705.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988; 54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.705 Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, all personnel who are involved in the furnishing of outpatient physical therapy, occupational therapy, and speech-language pathology services directly by or under arrangements with an organization must be legally authorized (licensed or, if applicable, certified or registered) to practice by the State in which they perform the functions or actions, and must act only within the scope of their State license or State certification or registration.

(b) *Exception for Federally defined qualifications.* The following Federally defined qualifications must be met:

(1) For a physician, the qualifications and conditions as defined in section

1861(r) of the Act and the requirements in part 484 of this chapter.

(2) *For a speech-language pathologist,* the qualifications specified in section 1861(11)(1) of the Act and the requirements in part 484 of this chapter.

(c) *Exceptions when no State Licensing laws or State certification or registration requirements exist.* If no State licensing laws or State certification or registration requirements exist for the profession, the following requirements must be met—

(1) An *administrator* is a person who has a bachelor's degree and:

(i) Has experience or specialized training in the administration of health institutions or agencies; or

(ii) Is qualified and has experience in one of the professional health disciplines.

(2) An *occupational therapist* must meet the requirements in part 484 of this chapter.

(3) An *occupational therapy assistant* must meet the requirements in part 484 of this chapter.

(4) A *physical therapist* must meet the requirements in part 484 of this chapter.

(5) A *physical therapist assistant* must meet the requirements in part 484 of this chapter.

(6) A *social worker* must meet the requirements in part 484 of this chapter.

(7) A *vocational specialist* is a person who has a baccalaureate degree and—

(i) Two years experience in vocational counseling in a rehabilitation setting such as a sheltered workshop, State employment service agency, etc.; or

(ii) At least 18 semester hours in vocational rehabilitation, educational or vocational guidance, psychology, social work, special education or personnel administration, and 1 year of experience in vocational counseling in a rehabilitation setting; or

(iii) A master's degree in vocational counseling.

(8) A *nurse practitioner* is a person who must:

(i) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law; and

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(ii) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners; *or*

(iii) Be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law and have been granted a Medicare billing number as a nurse practitioner by December 31, 2000; *or*

(iv) Be a nurse practitioner who on or after January 1, 2001, applies for a Medicare billing number for the first time and meets the standards for nurse practitioners in paragraphs (c)(8)(i) and (c)(8)(ii) of this section; *or*

(v) Be a nurse practitioner who on or after January 1, 2003, applies for a Medicare billing number for the first time and possesses a master's degree in nursing and meets the standards for nurse practitioners in paragraphs (b)(1)(i) and (b)(1)(ii) of this section.

(9) *A clinical nurse specialist* is a person who must:

(i) Be a registered nurse who is currently licensed to practice in the State where he or she practices and be authorized to perform the services of a clinical nurse specialist in accordance with State law;

(ii) Have a master's degree in a defined clinical area of nursing from an accredited educational institution; and,

(iii) Be certified as a clinical nurse specialist by the American Nurses Credentialing Center.

(10) *A physician assistant* is a person who:

(i) Has graduated from a physician assistant educational program that is accredited by the Commission on Accreditation of Allied Health Education Programs; *or*

(ii) Has passed the national certification examination that is administered by the National Commission on Certification of Physician Assistants; and

(iii) Is licensed by the State to practice as a physician assistant.

[63 FR 58912, Nov. 2, 1998; 64 FR 25457, May 12, 1999; 64 FR 59442, Nov. 2, 1999]

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§ 485.707 Condition of participation: Compliance with Federal, State, and local laws.

The organization and its staff are in compliance with all applicable Federal, State, and local laws and regulations.

(a) *Standard: Licensure of organization.* In any State in which State or applicable local law provides for the licensing of organizations, a clinic, rehabilitation agency, or public health agency is licensed in accordance with applicable laws.

(b) *Standard: Licensure or registration of personnel.* Staff of the organization are licensed or registered in accordance with applicable laws.

[41 FR 20865, May 21, 1976, unless otherwise noted. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995]

§ 485.709 Condition of participation: Administrative management.

The clinic or rehabilitation agency has an effective governing body that is legally responsible for the conduct of the clinic or rehabilitation agency. The governing body designates an administrator, and establishes administrative policies.

(a) *Standard: Governing body.* There is a governing body (or designated person(s) so functioning) which assumes full legal responsibility for the overall conduct of the clinic or rehabilitation agency and for compliance with applicable laws and regulations. The name of the owner(s) of the clinic or rehabilitation agency is fully disclosed to the State agency. In the case of corporations, the names of the corporate officers are made known.

(b) *Standard: Administrator.* The governing body—

(1) Appoints a qualified full-time administrator;

(2) Delegates to the administrator the internal operation of the clinic or rehabilitation agency in accordance with written policies;

(3) Defines clearly the administrator's responsibilities for procurement and direction of personnel; and

(4) Designates a competent individual to act during temporary absence of the administrator.

(c) *Standard: Personnel policies.* Personnel practices are supported by appropriate written personnel policies that are kept current. Personnel records include the qualifications of all professional and assistant level personnel, as well as evidence of State licensure if applicable.

(d) *Standard: Patient care policies.* Patient care practices and procedures are supported by written policies established by a group of professional personnel including one or more physicians associated with the clinic or rehabilitation agency, one or more qualified physical therapists (if physical therapy services are provided), and one or more qualified speech pathologists (if speech pathology services are provided). The policies govern the outpatient physical therapy and/or speech pathology services and related services that are provided. These policies are evaluated at least annually by the group of professional personnel, and revised as necessary based upon this evaluation.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

**§485.711 Condition of participation:
Plan of care and physician involvement.**

For each patient in need of outpatient physical therapy or speech pathology services there is a written plan of care established and periodically reviewed by a physician, or by a physical therapist or speech pathologist respectively. The organization has a physician available to furnish necessary medical care in case of emergency.

(a) *Standard: Medical history and prior treatment.* The following are obtained by the organization before or at the time of initiation of treatment:

- (1) The patient's significant past history.
- (2) Current medical findings, if any.
- (3) Diagnosis(es), if established.
- (4) Physician's orders, if any.
- (5) Rehabilitation goals, if determined.
- (6) Contraindications, if any.

(7) The extent to which the patient is aware of the diagnosis(es) and prognosis.

(8) If appropriate, the summary of treatment furnished and results achieved during previous periods of rehabilitation services or institutionalization.

(b) *Standard: Plan of care.* (1) For each patient there is a written plan of care established by the physician or by the physical therapist or speech-language pathologist who furnishes the services.

(2) The plan of care for physical therapy or speech pathology services indicates anticipated goals and specifies for those services the—

- (i) Type;
- (ii) Amount;
- (iii) Frequency; and
- (iv) Duration.

(3) The plan of care and results of treatment are reviewed by the physician or by the individual who established the plan at least as often as the patient's condition requires, and the indicated action is taken. (For Medicare patients, the plan must be reviewed by a physician, nurse practitioner, clinical nurse specialist, or physician assistant at least every 30 days, in accordance with §410.61(e) of this chapter.)

(4) Changes in the plan of care are noted in the clinical record. If the patient has an attending physician, the therapist or speech-language pathologist who furnishes the services promptly notifies him or her of any change in the patient's condition or in the plan of care.

(c) *Standard: Emergency care.* The organization provides for one or more doctors of medicine or osteopathy to be available on call to furnish necessary medical care in case of emergency. The established procedures to be followed by personnel in an emergency cover immediate care of the patient, persons to be notified, and reports to be prepared.

[54 FR 38679, Sept. 20, 1989. Redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 63 FR 58913, Nov. 2, 1998]

**§ 485.713 Condition of participation:
Physical therapy services.**

If the organization offers physical therapy services, it provides an adequate program of physical therapy and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* (1) The organization is considered to have an adequate outpatient physical therapy program if it can:

(i) Provide services using therapeutic exercise and the modalities of heat, cold, water, and electricity;

(ii) Conduct patient evaluations; and

(iii) Administer tests and measurements of strength, balance, endurance, range of motion, and activities of daily living.

(2) A qualified physical therapist is present or readily available to offer supervision when a physical therapist assistant furnishes services.

(i) If a qualified physical therapist is not on the premises during all hours of operation, patients are scheduled so as to ensure that the therapist is present when special skills are needed, for example, for evaluation and reevaluation.

(ii) When a physical therapist assistant furnishes services off the organization's premises, those services are supervised by a qualified physical therapist who makes an onsite supervisory visit at least once every 30 days.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of disabilities it accepts for service.

(c) *Standard: Personnel qualified to provide physical therapy services.* Physical therapy services are provided by, or under the supervision of, a qualified physical therapist. The number of qualified physical therapists and qualified physical therapist assistants is adequate for the volume and diversity of physical therapy services offered. A qualified physical therapist is on the premises or readily available during the operating hours of the organization.

(d) *Standard: Supportive personnel.* If personnel are available to assist qualified physical therapists by performing

services incident to physical therapy that do not require professional knowledge and skill, these personnel are instructed in appropriate patient care services by qualified physical therapists who retain responsibility for the treatment prescribed by the attending physician.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2327, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

**§ 485.715 Condition of participation:
Speech pathology services.**

If speech pathology services are offered, the organization provides an adequate program of speech pathology and has an adequate number of qualified personnel and the equipment necessary to carry out its program and to fulfill its objectives.

(a) *Standard: Adequate program.* The organization is considered to have an adequate outpatient speech pathology program if it can provide the diagnostic and treatment services to effectively treat speech disorders.

(b) *Standard: Facilities and equipment.* The organization has the equipment and facilities required to provide the range of services necessary in the treatment of the types of speech disorders it accepts for service.

(c) *Standard: Personnel qualified to provide speech pathology services.* Speech pathology services are given or supervised by a qualified speech pathologist and the number of qualified speech pathologists is adequate for the volume and diversity of speech pathology services offered. At least one qualified speech pathologist is present at all times when speech pathology services are furnished.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2328, Jan. 9, 1995]

**§ 485.717 Condition of participation:
Rehabilitation program.**

This condition and its standards apply only to a rehabilitation agency's own patients, not to patients of hospitals, skilled nursing facilities (SNFs), or Medicaid nursing facilities (NFs) to whom the agency furnishes services. (The hospital, SNF, or NF is responsible for ensuring that qualified staff

furnish services for which they arrange or contract for their patients.) The rehabilitation agency provides, in addition to physical therapy and speech-language pathology services, social or vocational adjustment services to all of its patients who need them. The agency provides for special qualified staff to evaluate the social and vocational factors, to counsel and advise on the social or vocational problems that arise from the patient's illness or injury, and to make appropriate referrals for needed services.

(a) *Standard: Qualification of staff.* The agency's social or vocational adjustment services are furnished as appropriate, by qualified psychologists, qualified social workers, or qualified vocational specialists. Social or vocational adjustment services may be performed by a qualified psychologist or qualified social worker. Vocational adjustment services may be furnished by a qualified vocational specialist.

(b) *Standard: Arrangements for social or vocational adjustment services.* (1) If a rehabilitation agency does not provide social or vocational adjustment services through salaried employees, it may provide those services through a written contract with others who meet the requirements and responsibilities set forth in this subpart for salaried personnel.

(2) The contract must specify the term of the contract and the manner of termination or renewal and provide that the agency retains responsibility for the control and supervision of the services.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 11632, Mar. 2, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.719 Condition of participation: Arrangements for physical therapy and speech pathology services to be performed by other than salaried organization personnel.

(a) *Conditions.* If an organization provides outpatient physical therapy or speech pathology services under an arrangement with others, the services are to be furnished in accordance with the terms of a written contract, which provides that the organization retains

of professional and administrative responsibility for, and control and supervision of, the services.

(b) *Standard: Contract provisions.* The contract—

(1) Specifies the term of the contract and the manner of termination or renewal;

(2) Requires that personnel who furnish the services meet the requirements that are set forth in this subpart for salaried personnel; and

(3) Provides that the contracting outside resource may not bill the patient or Medicare for the services. This limitation is based on section 1861(w)(1) of the Act, which provides that—

(i) Only the provider may bill the beneficiary for covered services furnished under arrangements; and

(ii) Receipt of Medicare payment by the provider, on behalf of an entitled individual, discharges the liability of the individual or any other person to pay for those services.

[56 FR 46562, Sept. 13, 1991. Redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.721 Condition of participation: Clinical records.

The organization maintains clinical records on all patients in accordance with accepted professional standards, and practices. The clinical records are completely and accurately documented, readily accessible, and systematically organized to facilitate retrieving and compiling information.

(a) *Standard: Protection of clinical record information.* The organization recognizes the confidentiality of clinical record information and provides safeguards against loss, destruction, or unauthorized use. Written procedures govern the use and removal of records and the conditions for release of information. The patient's written consent is required for release of information not authorized by law.

(b) *Standard: Content.* The clinical record contains sufficient information to identify the patient clearly, to justify the diagnosis(es) and treatment, and to document the results accurately. All clinical records contain the following general categories of data:

(1) Documented evidence of the assessment of the needs of the patient, of

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an appropriate plan of care, and of the care and services furnished.

(2) Identification data and consent forms.

(3) Medical history.

(4) Report of physical examinations, if any.

(5) Observations and progress notes.

(6) Reports of treatments and clinical findings.

(7) Discharge summary including final diagnosis(es) and prognosis.

(c) *Standard: Completion of records and centralization of reports.* Current clinical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's clinical record. Each physician signs the entries that he or she makes in the clinical record.

(d) *Standard: Retention and preservation.* Clinical records are retained for at least:

(1) The period determined by the respective State statute, or the statute of limitations in the State; or

(2) In the absence of a State statute—

(i) Five years after the date of discharge; or

(ii) In the case of a minor, 3 years after the patient becomes of age under State law or 5 years after the date of discharge, whichever is longer.

(e) *Standard: Indexes.* Clinical records are indexed at least according to name of patient to facilitate acquisition of statistical medical information and retrieval of records for research or administrative action.

(f) *Standard: Location and facilities.* The organization maintains adequate facilities and equipment, conveniently located, to provide efficient processing of clinical records (reviewing, indexing, filing, and prompt retrieval).

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2328, Jan. 9, 1995]

§ 485.723 Condition of participation: Physical environment.

The building housing the organization is constructed, equipped, and maintained to protect the health and safety of patients, personnel, and the public and provides a functional, sanitary, and comfortable environment.

(a) *Standard: Safety of patients.* The organization satisfies the following requirements:

(1) It complies with all applicable State and local building, fire, and safety codes.

(2) Permanently attached automatic fire-extinguishing systems of adequate capacity are installed in all areas of the premises considered to have special fire hazards. Fire extinguishers are conveniently located on each floor of the premises. Fire regulations are prominently posted.

(3) Doorways, passageways and stairwells negotiated by patients are:

(i) Of adequate width to allow for easy movement of all patients (including those on stretchers or in wheelchairs), (ii) free from obstruction at all times, and (iii) in the case of stairwells, equipped with firmly attached handrails on at least one side.

(4) Lights are placed at exits and in corridors used by patients and are supported by an emergency power source.

(5) A fire alarm system with local alarm capability and, where applicable, an emergency power source, is functional.

(6) At least two persons are on duty on the premises of the organization whenever a patient is being treated.

(7) No occupancies or activities undesirable or injurious to the health and safety of patients are located in the building.

(b) *Standard: Maintenance of equipment, building, and grounds.* The organization establishes a written preventive-maintenance program to ensure that—

(1) The equipment is operative, and is properly calibrated; and

(2) The interior and exterior of the building are clean and orderly and maintained free of any defects that are a potential hazard to patients, personnel, and the public.

(c) *Standard: Other environmental considerations.* The organization provides a functional, sanitary, and comfortable environment for patients, personnel, and the public.

(1) Provision is made for adequate and comfortable lighting levels in all areas; limitation of sounds at comfort levels; a comfortable room temperature; and adequate ventilation through

windows, mechanical means, or a combination of both.

(2) Toilet rooms, toilet stalls, and lavatories are accessible and constructed so as to allow use by non-ambulatory and semiambulatory individuals.

(3) Whatever the size of the building, there is an adequate amount of space for the services provided and disabilities treated, including reception area, staff space, examining room, treatment areas, and storage.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326-2328, Jan. 9, 1995]

§ 485.725 Condition of participation: Infection control.

The organization that provides outpatient physical therapy services establishes an infection-control committee of representative professional staff with responsibility for overall infection control. All necessary housekeeping and maintenance services are provided to maintain a sanitary and comfortable environment and to help prevent the development and transmission of infection.

(a) *Standard: Infection-control committee.* The infection-control committee establishes policies and procedures for investigating, controlling, and preventing infections in the organization and monitors staff performance to ensure that the policies and procedures are executed.

(b) All personnel follow written procedures for effective aseptic techniques. The procedures are reviewed annually and revised if necessary to improve them.

(c) *Standard: Housekeeping.* (1) The organization employs sufficient housekeeping personnel and provides all necessary equipment to maintain a safe, clean, and orderly interior. A full-time employee is designated as the one responsible for the housekeeping services and for supervision and training of housekeeping personnel.

(2) An organization that has a contract with an outside resource for housekeeping services may be found to be in compliance with this standard provided the organization or outside resource or both meet the requirements of the standard.

(d) *Standard: Linen.* The organization has available at all times a quantity of linen essential for proper care and comfort of patients. Linens are handled, stored, processed, and transported in such a manner as to prevent the spread of infection.

(e) *Standard: Pest control.* The organization's premises are maintained free from insects and rodents through operation of a pest-control program.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326, 2328, Jan. 9, 1995; 60 FR 50447, Sept. 29, 1995]

§ 485.727 Condition of participation: Disaster preparedness.

The organization has a written plan, periodically rehearsed, with procedures to be followed in the event of an internal or external disaster and for the care of casualties (patients and personnel) arising from a disaster.

(a) *Standard: Disaster plan.* The organization has a written plan in operation, with procedures to be followed in the event of fire, explosion, or other disaster. The plan is developed and maintained with the assistance of qualified fire, safety, and other appropriate experts, and includes:

- (1) Transfer of casualties and records;
- (2) The location and use of alarm systems and signals;
- (3) Methods of containing fire;
- (4) Notification of appropriate persons; and
- (5) Evacuation routes and procedures.

(b) *Standard: Staff training and drills.* All employees are trained, as part of their employment orientation, in all aspects of preparedness for any disaster. The disaster program includes orientation and ongoing training and drills for all personnel in all procedures so that each employee promptly and correctly carries out his assigned role in case of a disaster.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977, and amended at 53 FR 12015, Apr. 12, 1988. Redesignated and amended at 60 FR 2326-2327, 2329, Jan. 9, 1995]

§ 485.729 Condition of participation: Program evaluation.

The organization has procedures that provide for a systematic evaluation of its total program to ensure appropriate

utilization of services and to determine whether the organization's policies are followed in providing services to patients through employees or under arrangements with others.

(a) *Standard: Clinical-record review.* A sample of active and closed clinical records is reviewed quarterly by the appropriate health professionals to ensure that established policies are followed in providing services.

(b) *Standard: Annual statistical evaluation.* An evaluation is conducted annually of statistical data such as number of different patients treated, number of patient visits, condition on admission and discharge, number of new patients, number of patients by diagnosis(es), sources of referral, number and cost of units of service by treatment given, and total staff days or work hours by discipline.

[41 FR 20865, May 21, 1976. Redesignated at 42 FR 52826, Sept. 30, 1977. Further redesignated and amended at 60 FR 2326–2327, 2329, Jan. 9, 1995]

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

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APPENDIX A TO SUBPART G OF PART 486—
GUIDELINES FOR PREVENTING TRANSMISSION OF HUMAN IMMUNODEFICIENCY VIRUS THROUGH TRANSPLANTATION OF HUMAN TISSUE AND ORGANS

AUTHORITY: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

§ 486.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following sections of the Act: